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Herbert Chao

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EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/799,431	Applicant(s) CHAO ET AL.	
	Examiner Jeffrey T. Palenik	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-22 is/are rejected.
- 7) ☒ Claim(s) 8,9 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' timely filed Amendments and Remarks of 12 January 2010. Said remarks and amendments are entered on the record. The Examiner further acknowledges the following:

Claims 1-31 remain pending with claims 23-30 remaining withdrawn from consideration. No claims have been added, cancelled or amended.

Thus, no new matter has been added.

As such, claims 1-22 and 31 continue to represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for review or consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Rejections under 35 USC 112

Applicants' amendments made to claims 2 and 6 concerning the recited ratios as well as to claim 10 concerning the lack of antecedent basis for the term "copolymer" are sufficient enough to render the rejections to these claims under 35 USC 112, second paragraph moot. Thus said rejections are **withdrawn**.

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Applicants' submission of the MSDS data in response to the Request for Information, is sufficient enough to overcome the written description rejection made to claims 8 and 9 under 35 USC 112, first paragraph. This rejection is **withdrawn**.

Applicants' remarks concerning the rejection to claims 1-22 and 31 concerning the enablement for the use of "carboxyl-terminated polymers", particularly those which state "that only the polymers disclosed in paragraphs [0017] and [0018] are enabled", have been fully considered and are persuasive enough to overcome the rejection made under 35 USC 112, first paragraph. This rejection is **withdrawn**.

Applicants' remarks concerning the rejection to claims 4, 5, 8 and 9 under 35 USC 112, second paragraph, have been fully considered and are persuasive, in part. As discussed in the instant specification, Applicants clearly discuss that the major component "typically makes up at least 90% by weight of the polyacid...". Applicants' remarks state that "[o]ne skilled in the art would no doubt interpret said term as more than half, whereas "minor component" would be interpreted as less than half." However, there is no support in the instant disclosure that the presence of this component ranges from greater than 50% to less than 90% (i.e. the other amounts embodied by a "majority component"). As such, the rejection is **withdrawn**. However, the limitations concerning the recitation of claims 4 and 8, and as interpreted in light of the specification, is that the term "major component" is defined as pertaining to 90% by weight or more of the polyacid (e.g. as recited in claims 5 and 9).

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Rejections under Double Patenting

Applicants' remarks concerning the rejection of claims 1-7, 10-16, and 18-22 on the grounds of non-statutory obviousness-type double patenting over Chapin et al. (USPN 4,594,380) were considered persuasive by the Examiner. Though inadvertently not addressed in the previous Office Action, Applicants' present assumption is correct in that this rejection stands **withdrawn**.

MAINTAINED OBJECTION/REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 15 October 2009 since the art which was previously cited continues to read on the limitations.

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention [*emphasis added to reflect rejections not yet overcome*].

Claims 11 and 12 recite the limitation "the carboxyl-terminated copolymer" in the first line of each claim. There is insufficient antecedent basis for each of these limitations in claim 1.

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RESPONSE TO ARGUMENTS

Applicants' remarks with regard to the lack of antecedent basis rejection of claims 11 and 12 under 35 USC 112, second paragraph, have been fully considered but they are not persuasive.

Applicants state in their response that the claims have been amended to overcome the rejection.

In response, the Examiner respectfully maintains that claims 11 and 12 do not reflect the change stated by Applicants. The Examiner also acknowledges that this was inadvertently missed in the last Office Action.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 10-16 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapin et al. (USPN 4,594,380).

The instant claims are directed to a continuous-release composition comprising an elastomeric matrix and at least one active agent wherein said matrix is the reaction product of a carboxyl-terminated polymer and a polycarbodiimide (claims 1, 2, 6, 10-12, 14 and 22). With regard to the limitation of claim 1, wherein "the active agent being released from the matrix into

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the environment substantially continuously over an extended period of time”, is considered by the Examiner as a functional limitation of the instantly claimed composition; it is a limitation expected of a continuous release composition. With regard to the limitations respectively recited in claims 2 and 6, which state “wherein the ratio of polycarbodiimide to carboxyl-terminated polymer is 0.7 to 6.0” and “...is 0.7 to 1.4”, until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the elastomeric matrix composition which is instantly claimed. Regarding the limitation of claims 10-12 wherein the carboxyl terminated copolymer of claim 1 is the reaction product of a mixture...”, is deemed by the Examiner as being a product-by-process limitation, which per MPEP §2113, holds no patentable weight. Regarding the limitations recited in claims 11 and 12 which are directed to the percent composition of the carboxyl-terminated copolymer, said recitations are deemed by the Examiner as being functional limitations to product-by-process limitations and similarly hold no patentable weight. The functionality limitation as recited in claim 14, is considered an inseparable property of the polycarbodiimide component of the matrix composition (see MPEP §2112.01(II)). The limitation “in the form of a gel” recited in claim 22 is deemed one of intended use and holds no patentable weight with regards to the instantly claimed composition. Hydrophobic carboxyl-terminated polymers are recited (claim 3). Types of polycarbodiimides used are recited (claim 13). The composition further comprising one or more inert (e.g. non-biologically active) agents is recited (claims 15 and 16). Dissolution or dispersal of the active agent(s) in the matrix is recited (claims 18 and 19). Percentage of the active(s) in the matrix is recited (claim 20). A fragrance as the active agent(s) is recited (claim 21).

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Chapin et al. teach an article comprising an elastomeric matrix and at least one biologically or non-biologically active agent in the matrix which is continuously released over an extended period of time (claim 1). Said matrix is taught as comprising polyurethane which is formed by reacting a polyol with an isocyanate (claim 1). Though the term “polycarbodiimide” is not expressly used in the teachings of Chapin, the polyurethane which is formed from the reaction of Chapin in claim 1, is polycarbodiimide as defined by Torimae et al. (USPN 4,221,572) wherein the toluene diisocyanate and polyols are reacted to form polycarbodiimide compounds (Abstract and Example 1). The same reaction is performed by Chapin wherein the reacted polyol comprises hydroxyl-terminated and carboxyl-terminated components and the isocyanates used comprise aromatic, aliphatic, cycloaliphatic and heterocyclic isocyanates having functionalities greater than 2 (e.g. between 2 and 3) (claims 1 and 2). The instantly claimed hydrophobic carboxyl-terminated polymers are taught in claim 2. The polyol taught in claim 1 is taught as a copolymer of hydroxyl- and carboxyl-terminated polymers, the resulting copolymer having a molecular weight ranging from 400-10,000. Claim 3 teaches the composition as further comprising inert components such as fillers, plasticizers, stabilizers, pigments and fungicides. Claim 4 teaches fragrances (e.g. deodorants, air fresheners, perfumes, attractants and repellents) as the active agent. Claims 9 and 10 respectively teach the active agent as being dissolved and dispersed in the matrix. Claim 8 teaches the active agent as comprising 10-50% by weight of the article. Therefore, all the limitations of the claimed invention are met by the reference to Chapin et al.

PREVIOUS RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-3, 6, 10-16 and 18-22 under 35 USC 102(b) as being anticipated by Chapin et al. (USPN 4,594,380), has been fully considered, but is not persuasive.

Applicants argue that the composition prepared by Chapin is a polyurethane which is made by reaction of a polyol with a polyisocyanate and that Chapin does not disclose a polycarbodiimide. Applicants further state on the record that "[a] polycarbodiimide is typically prepared by polymerizing a polyisocyanate itself, such as toluene diisocyanate or diphenyl methane diisocyanate".

In response, the Examiner respectfully disagrees submits that the composition which is taught as being prepared in claims 1 and 2 of Chapin is considered as reading on the composition recited by the instant base claim. Claim 1 of Chapin teaches an article comprising an elastomeric matrix and at least one active agent contained within the matrix, wherein said matrix is prepared by reacting a polyol with an isocyanate [*emphasis added*]. Chapin further defines and sets forth preferred isocyanates as being polyarylene isocyanates which are taught further still as being prepared from aromatic isocyanates such as 2,4 toluene diisocyanate, and 2,6 toluene diisocyanate, mixtures thereof, and 4,4' diphenyl methane diisocyanate and its oligomers (col. 5, lines 50-56). Diisocyanates, such as the aforementioned, are well known in the art as being used to produce preferred unhindered aromatic polycarbodiimides. See for example Brown et al. (USPN 3,835,098; col. 4, lines 14-40).

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Thus, for these reasons, Applicants' arguments are found unpersuasive. The above rejection is hereby **maintained**.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5, 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Chapin with respect to claim 1 as set forth above.

The instant invention is drawn to a continuous release composition comprising an elastomeric matrix which is the reaction product of a carboxyl-terminated polymer and a polycarbodiimide, as discussed above. Also as discussed above, claims 4 and 5 recite that said carboxyl-terminated polymer is both hydrophobic and selected from a group of polymers such as

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carboxyl-terminated polybutadiene and carboxyl-terminated copolymers of polybutadiene with acrylonitrile and that said polymers represent at least 90% by weight of the carboxyl-terminated polymer. Claims 7 and 17 each further limit the carboxyl-terminated polymer of claim 1 in terms of its molecular weight, ranging from 1,000 to 20,000 and 1,000 to 10,000, respectively. Claim 17 further recites that the carboxyl-terminated polymer has an average carboxylic acid functionality ranging from 1.8-8.0. With regard to the functionality limitation recited in claim 17; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the instantly claimed carboxyl-terminated polymer having a molecular weight which reads on the instantly claimed weight range.

The teachings of Chapin are discussed above. Chapin further teaches that the polyurethane elastomer is formed using a process which reacts polyols with isocyanates, wherein carboxyl-terminated polymers are expressly taught as optional minor components (col. 3, lines 7-10 and lines 18-26). The compounds which are expressly taught by the passage read on those which are recited in claim 4. Said carboxyl-terminated polymers are taught as having a molecular weight ranging from 400 to 10,000, which teaches the limitations of claims 7 and 17. The “major component” limitations, as discussed above with regards to claims 4 and 5, are considered as being expressly taught by the passage.

Thus, in view of the express teachings provided by Chapin, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the invention to have prepared a polyurethane elastomer by mixing a carboxyl-terminated polymer with an isocyanate in order to achieve the instantly claimed composition. The ordinarily skilled artisan would have been

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highly motivated to do so particularly in view of two points. First, the aforementioned discussion of the term “isocyanate” per Chapin preferably teaches that such a compound includes polymers, oligomers and mixtures of 2,4- and 2,6-toluene diisocyanate, and diphenyl methane diisocyanate compounds. As discussed above, polymerization of such compounds is well known in the art as the formation of polycarbodiimides. Further, per the discussion above regarding the carboxyl-terminated polymer and the indefinite recitation of “a major component”, the Examiner interprets said limitation in light of Applicants’ disclosure as setting forth that the carboxyl-terminated polymer comprises at least 90 wt% of compounds such as carboxyl-terminated butadiene or CT copolymers of butadiene with acrylonitrile (see claims 4 and 5). Said compounds are expressly taught by Chapin, albeit as optional compounds, as being available in the art for selection as the carboxyl-terminated polymer. As such, were the skilled artisan to select one of these compounds to prepare the elastomer matrix, it follows that it would comprise 100% of the carboxyl-terminated polymer (e.g. the “major component”). The ordinarily skilled artisan would be motivated further still to incorporate the optional carboxyl-terminated polymers into the elastomer formulation in the interest of altering or adjusting the cross-link density of the final elastomer matrix. Such an adjustment is expressly taught as influencing the ability of the formulation to release the active compound embedded within (col. 5, lines 1-7).

Thus, based on the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-3, 6, 10-16 and 18-22 under 35 USC 102(b) as being anticipated by Chapin et al., as well as the rejection of claims 4, 5, 7 and 17 under 35 USC 103(a) as being unpatentable over the teachings of Chapin et al., have both been fully considered, but neither are persuasive.

Applicants continue to allege that the composition of claim 1 is not taught by the Chapin reference further stating that "Chapin does not disclose a polycarbodiimide" and that "[a] polycarbodiimide is not an isocyanate and an isocyanate is not a polycarbodiimide".

In response, the Examiner respectfully maintains the positions that the Chapin reference does not expressly use the term polycarbodiimide, but despite this, the reference continues to read upon and anticipate the base claim, contrary to Applicants' allegation.

The interpretation of the base claim is that continuous release composition comprises at least one active agent which is embedded within an elastomeric matrix. The elastomeric matrix is "the reaction product of a carboxyl-terminated polymer with a polycarbodiimide". The quoted limitation is broadly and reasonably interpreted by the Examiner as reciting that the matrix is formed by mixing together the two components. Since the composition "comprises" these components, additional components taught by the art which may be present in the composition are not precluded from being present (MPEP §2111.03).

The first component and embodiments thereof are taught in the claims of Chapin (see claim 2).

The second component (e.g. polycarbodiimide) is considered as being taught in that claim

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1, part b) of the Chapin reference teaches that the isocyanate component of the composition comprises mixtures of aromatic, cycloaliphatic, aliphatic and heterocyclic isocyanates. The functionality of isocyanate component taught is further taught as ranging from 2-3. That the isocyanate component comprises mixtures of isocyanates is interpreted by the Examiner as being a teaching of polymers of isocyanates. Combination of the aforementioned isocyanates is known in the art as leading to the production of polycarbodiimides as evidenced by Brown et al. (USPN 3,835,098; col. 4, lines 14-40), discussed above. Further evidence of this is presented by Misumi et al. (USPN 6,248,857) which teach that the preparation of polycarbodiimides occurs from combining isocyanate monomers (col. 7, line 50 to col. 9 line 30). What catalysts, binders or other excipients used to prepare such a compound or the ensuing matrix, are once again, not presently precluded by the limitations of the instant base claim.

For these reasons, Applicants' arguments are found unpersuasive. Said rejections are therefore **maintained**.

ALLOWABLE SUBJECT MATTER

Claims 8, 9, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The remaining claims remain rejected.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615